

# CSUF Animal Care and Use Handbook

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# **California State University, Fullerton Animal Care and Use Handbook 2025**

## **PREFACE**

### **Purpose of This Handbook**

California State University, Fullerton is committed to the ethical and humane care and use of animals. Each person involved in animal care or use shares the responsibility in meeting this commitment.

Faculty, staff and students who work with animals have an obligation to know about ethical concerns relevant to the care and use of animals and to observe the guidelines and policies established by government agencies, scientific societies and this institution.

This handbook is designed to help meet those obligations and to provide information about the procedures for animal care and use on this campus. For more information on IACUC or for additional copies of this handbook, please visit the Office of Research and Sponsored Programs (ORSP) website <http://www.fullerton.edu/doresearch/compliance/iacuc.php> or contact one of the following:

IACUC Coordinator, 657-278-7719  
Chair, Institutional Animal Care and Use Committee, 657-278-2849  
Office of Research and Sponsored Programs (ORSP)  
2<sup>nd</sup> Floor, Titan Hall, 1121 North State College Blvd.  
Fullerton, CA 92831-3014 USA

### ***Acknowledgments***

We thank our colleagues at other institutions who freely provided some of the material presented here. Persons in Research Administration and Laboratory Animal Science traditionally share information, published or unpublished, because we believe that collaboration results in the development of good policies and procedures. We believe that this process ensures that the animals used in instruction and research receive the most humane care possible. Special thanks to California State Polytechnic University, San Jose State University, and other institutions for portions of this material.

Considerable effort has been made to ensure that the information provided here is accurate. However, if errors of any kind are identified, please notify the IACUC Coordinator as soon as possible. This handbook, along with others of its kind, is considered a “living document,” subject to change in light of new information and changing conditions.

## **I. GENERAL INFORMATION**

### **A. How to Use This Handbook**

This handbook details the responsibilities of faculty, staff and students who use animals in teaching or research. Section I provides an overview of responsibilities and the applicable federal and state laws. Section II describes the roles and functions of those administering or participating in the care or use of animals. Section III covers the circumstances where review and approval is required, and Section IV discusses the procedures for securing approval. Section V explains the policies and procedures related to animal use and housing. Special situations for animal use or housing are covered in Section VI. Section VII covers hazards and security and Section VIII covers supervision and training issues for those working with animals.

### **B. Statement of Commitment**

California State University, Fullerton is committed to the humane care and use of animals. This commitment is reflected in the presence of an accredited and state-licensed Veterinarian and Animal Care Facility Specialist, who have as their principal concern the health and welfare of animals on campus. The University has a designated Institutional Animal Care and Use Committee (IACUC), which is composed of a panel of experts on animal health and welfare, life and behavioral sciences, and federal regulations, but also has representation of community concerns. These individuals review activities involving live vertebrate animals in teaching and research. Each protocol is reviewed by the IACUC to ensure that the use of animals is justified, that the number of animals used is appropriate, and that the procedures are done in a humane fashion.

They are guided in part by law, as dictated through the Animal Welfare Act and related regulations (administered by the United States Department of Agriculture USDA). As required by law, the IACUC conducts a semi-annual review of institutional programs for the humane care and use of animals and also conducts semi-annual inspections of all facilities where animals are held more than 12 hours and animal use areas. Their findings are reported to the university's Institutional Official and to the National Institutes of Health (NIH), which, through the Office of Laboratory Welfare (OLAW) oversees animal care and use at institutions receiving NIH funding. These findings are also reviewed by the USDA during its semi-annual unannounced inspections. California State University, Fullerton adheres to the regulations published by the USDA as well as to the recommendations and guidelines set forth by the National Institutes of Health in the "*Guide for the Care and Use of Laboratory Animals*" and other policy statements. These regulations and guidelines dictate stringent requirements for the animals' environment, including light, temperature, humidity, etc., as well as their daily care and veterinary needs. Finally, as part of these requirements and its commitment to animal welfare, the university has procedures in place for reporting concerns regarding animal care and use on campus. Individuals with concerns may

approach the IACUC Chair, the Campus Veterinarian, the Animal Care Facility Specialist, or the Principal Investigator (PI) of a particular project with their concerns.

### C. Faculty and Staff Responsibilities

All faculty, staff and students using vertebrate animals should be aware of the general policies contained in this handbook. Individual faculty and staff members who are involved with the care and use of animals in instruction and research, including field studies of live vertebrates, are expected to study and review this handbook, and to acknowledge their acceptance of the responsibilities therein. These regulations and policies cover: (a) the acquisition, care and use of animals, (b) efforts to minimize animal pain and distress, (c) the training of personnel involved in the use of animals, and (d) considerations of alternatives to animal use. All faculty, staff and research students individuals using vertebrate animals must also complete an online course *"Using Animal Subjects in Research"* through the Collaborative Institutional Training Initiative (CITI) Program; this course must be re-taken every 4 years. Many of the general topics in this Handbook are discussed in the CITI course.

### D. Animal Welfare and Other Related Laws, Policies and Regulations

The use of animals in teaching and research is closely regulated by the federal government. In addition, other federal, state and local regulations may affect specific aspects of animal care and use (such as housing). Finally, some independent professional organizations also publish guidelines for the care and use of animals for investigators and campus personnel. Knowledge and compliance of regulations is important, as the penalties for non-compliance can be far-reaching. **Both USDA and NIH have the power to suspend or discontinue all or part of the animal care and use activities on campus, should the campus fail to comply with regulations and policies.** Furthermore, federal funding agencies, such as NIH and the National Science Foundations (NSF), may withdraw funding of a specific project or all projects should compliance not be met.

#### 1. Federal Level

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS) OF THE U.S. DEPARTMENT OF AGRICULTURE (USDA): USDA-APHIS administers the Federal Animal Welfare Act, which establishes animal care standards for many species of laboratory animals. Compliance requirements include establishment of programs of adequate veterinary care, maintenance of records of the acquisition and disposition of research animals, and submission of an annual report showing the total numbers of laboratory animals used in research and teaching, numbers of animals that receive anesthetics, analgesics, and sedatives for potential pain or distress, and numbers of animals used under conditions of unalleviated pain or distress. Periodic unannounced inspections are conducted by USDA-APHIS personnel.

**PUBLIC HEALTH SERVICE (PHS):** The Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals (revised in 2015) specifies the policies and procedures required of institutions. Current PHS policy requires institutional review of all research projects involving live vertebrate animals by an IACUC and specifies the composition and functions of the committee. PHS will not release funds for any research project until it receives a letter of verification from the institution (campus) stating that the proposal has received such committee review. PHS policy also requires the campus to file an Animal Welfare Assurance with NIH, in which the campus agrees to comply with NIH policy. NIH, a subdivision of the US Public Health Service (PHS), is a major source of grants for research in the health sciences. OLAW is the division within NIH that oversees animal care and use in PHS-funded research. The Institute for Laboratory Animal Research (ILAR) publishes the *"Guide for the Care and Use of Laboratory Animals"* (8<sup>th</sup> Edition was published in 2011), which establishes standards for the construction of vivaria, the care of animals, and the use of animals in research. Adherence to the *Guide* is mandatory for institutions receiving funds from NIH.

**DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT AGENCY (DEA):** The DEA enforces the Controlled Substances Act of 1970, which covers potentially addictive or habituating drugs for human or animal use. The DEA requires appropriate security and record management of these substances.

**U.S. FISH AND WILDLIFE SERVICE (USFWS):** This agency enforces the Endangered Species Act of 1973, which seeks "to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of endangered species and threatened species, and to achieve the purposes of the treaties and the conservation of wild flora and fauna world-wide." Implementing rules and regulations are included in the CFR, Title 50.

**U.S. GOVERNMENT:** The U.S. government has established principles for the Utilization and Care of Vertebrate Animals used in testing, research and training. These principles are detailed in Appendix A.

## **2. State Level**

**CALIFORNIA DEPARTMENT OF FISH AND WILDLIFE:** This agency administers State law that regulates the importation and containment of non-indigenous wildlife species and the collection and use of California wildlife species (California Administrative Code, Title 14, Sections 671-671.4).

**CALIFORNIA OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (CAL-OSHA):** Cal-OSHA administers detailed regulations pertaining to employee occupational health and safety, including potential health hazards to persons who work with animals.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH: This agency interacts with campus animal care authorities in the investigation of reportable infectious human diseases involving possible animal sources. Compliance requirements may involve such activities as posting of potentially hazardous animal areas and monitoring by the Campus Veterinarian.

### **3. Independent Professional Organizations**

INDEPENDENT PROFESSIONAL ORGANIZATIONS: Many professional organizations and societies also publish guidelines, manuals, and other information regarding animal care and use. They may also provide informational conferences, training and certification. These organizations include the American Veterinary Medical Association (AVMA) American Association for Laboratory Animal Science (AALAS), the American Association for the Accreditation of Laboratory Animal Care (AAALAC), the American College of Laboratory Animal Medicine (ACLAM), Applied Research Ethics National Association (ARENA), the Institute of Laboratory Animal Resources (ILAR), Public Responsibility in Medical Research (PRIMR), and Scientists' Center for Animal Welfare (SCAW).

In addition, many scientific societies have developed guidelines of their own. These guidelines are especially important for providing detail on topics not fully addressed in government regulations. Examples include *the American Psychological Association* (Guidelines for Ethical Conduct in the Care and Use of Animals); the *American Society of Mammalogists* (Acceptable Field Methods in Mammalogy); the *American Ornithologists Union* (Guidelines for the Use of Wild Birds in Research); and the *American Society of Ichthyologists and Herpetologists*: (Guidelines for the Use of Fishes in Field Research and Guidelines for the Use of Reptiles and Amphibians in Field Research). Copies of these publications are available on the ORSP website or through the IACUC Office. Awareness of federal, state and professional guidelines is important because refereed journals require compliance with pertinent IACUC guidelines before accepting papers for publication.

## **II. ROLES IN ANIMAL CARE AND USE**

### **A. Institutional**

Federal regulations require that all research facilities using animals register and certify that they will comply with applicable regulations. These institutions are responsible for appropriate record-keeping, facility inspection, provision of appropriate veterinary care, review of all activity using animals, and for supplying annual reports certifying compliance. The institution is also required to form an Institutional Animal Care and Use Committee (IACUC), which may carry out some of the tasks noted above. At CSUF, these activities are divided between the following areas:



## **1. Administrative**

The Associate Vice President for Research and Sponsored Programs serves as the Institutional Official (IO) for animal care regulations. The Institutional Official certifies compliance with federal regulations to the federal agencies on an annual basis, sends interim reports of any problems to the federal agencies, and receives reports from the IACUC and the Veterinarian.

The Office of Research and Sponsored Programs (ORSP) is the academic service unit that is responsible for managing and administering a centralized program of compliance with local, state and federal regulations. The Research Compliance Specialist (IACUC Coordinator) in that office and the IACUC Chair provide guidance on regulations, assistance on protocols, and administrative support to the IACUC.

## **2. Animal Care Facility Specialist and Campus Veterinarian**

The Animal Care Facility Specialist is responsible for daily animal husbandry and care, veterinary care, provision of information and technical assistance, monitoring the animals' environment, training of research and technical personnel who use live animals for instruction and research, and consultation and service in all phases of animal care and use. The Animal Care Facility Specialist may also assist Principal Investigators in ordering animals. The Specialist reports to the Department of Biological Science.

CSUF has contracted with a Veterinarian who is qualified to work with both lab animals and wild animals. The Veterinarian reviews all proposed animal care and use activities on campus. The Veterinarian (or his/her designee) are responsible for the supervision of animal disease control and prevention, euthanasia, appropriate use of anesthesia and analgesia, and other aspects of veterinary care specified in the Animal Welfare Act.

## **3. Institutional Animal Care and Use Committee (IACUC)**

Both the PHS Policy and Animal Welfare Act mandate the appointment of an IACUC, qualified through the experience and expertise of its members to assess and oversee the institution's animal program, facilities and procedures. CSUF has a single, university-wide IACUC. The IACUC oversees animal use throughout the University, as well as animal use by CSUF investigators off-site, and reports to the Institutional Official. The IACUC members are drawn principally from faculty who use live vertebrate animals in research and/or teaching, but also include a veterinarian and a non-scientist, non-affiliated community member. The IACUC functions as an agent of the University and is specifically charged with:

- a. Conducting a semi-annual review of the University's program for the humane care and use of vertebrate animals.
- b. Conducting a semi-annual inspection of the University's animal facilities and laboratories where animals are used and housed.
- c. Reviewing and approving proposed and on-going animal protocols.
- d. Investigating, suspending, or terminating protocols not in compliance with regulations and policies.
- e. Ensuring that all persons working with animals are properly trained to do so.

By law, the IACUC has the authority to shut down activities that are in violation of federal regulations.

#### **4. Other Campus Offices**

Other campus offices may also advise, coordinate, or regulate aspects of animal care and use. Environmental Health and Safety (EH&S) is responsible for the review and recommendations regarding occupational health issues related to animal care and use, through the Animal Care and Use Occupational Health Program. EH&S is the campus unit charged with responsibility for administering occupational health and safety programs, including medical health screening for risks related to animal exposure, accident prevention, and industrial hygiene. It is also responsible for review and recommendations regarding the use of radiation, biohazards, controlled substances, and hazardous chemicals. EH&S also supervises animal carcass disposal.

#### **B. Principal Investigator (PI)**

The principal investigator (PI) is the person who has responsibility for a specific research project. Only CSUF full-time faculty may serve as the PI of an IACUC-approved protocol. Emeritus faculty may serve as PIs with written approval of the current chair of their home department. In the case of research projects of graduate and undergraduate students and postdoctoral scholars, the supervising faculty member serves as PI. The PI is accountable by law to comply with the rules and regulations of applicable statutes. They are also accountable to conform with the policies and guidelines adopted by this institution. This responsibility includes the training and supervision of all personnel working under the PI on a research project or instructional activity. The responsibilities of the PI also include the following:

##### **1. Designs experiments.**

- a. Selects the appropriate species, model, animal quality, and source; consults with a statistician to determine the minimum number of animals required for valid data analysis.
- b. Considers previous work done in the area of study, using resources such as the databases of the National Agricultural Library and National Library of Medicine.

- c. Considers possible alternatives to living animals as subjects.
- d. Ensures that studies will not unnecessarily duplicate previous experiments.
- e. Establishes procedures and environments that minimize internal and external influences on experimental animals.
- f. Avoids, prevents, or minimizes animal discomfort, distress, and pain consistent with sound scientific practice.
- g. Uses appropriate endpoints for studies and acceptable procedures for euthanasia based on the most recent guidelines approved by the AVMA.
- h. Conducts all research in accordance with protocols approved by the IACUC.
- i. Obtains IACUC approval before instituting significant changes in a protocol.
- j. Procures all laboratory and wild animals in accordance with all relevant federal, state, and institutional regulations and policies.
- k. Maintains adequate records.
- l. Promptly files all necessary reports (e.g. student training, annual reviews).

**2. Ensures staff qualifications and training.**

- a. Recruits personnel qualified by background and temperament to work with animals.
- b. Orients personnel to the facility and the scientific study.
- c. Requires that staff members demonstrate skill with the techniques and procedures involved, and provides training as needed.
- d. Ensures that staff members are able to recognize signs of disease and distress in animals and know to whom to report any such signs.
- e. Provides or identifies continuing education and research compliance programs for staff and encourages participation in such programs.

**3. Provides for health and safety of personnel.**

- a. Ensures that staff and students have had instruction and training about zoonotic diseases, allergies to animals, disease prevention, etc., and that they participate in the Animal Care and Use Occupational Health Program.
- b. Ensures that staff have received detailed instructions on proper procedures for using hazardous substances and pathogenic organisms, including the requirement for protective clothing appropriate for the species of animal and the protocol.

**4. Makes provisions for dealing with job-related stress.**

- a. Identifies activities and procedures that might be stressful to personnel, including euthanasia, long-term studies, and studies using animals generally regarded as pets.
- b. Provides opportunities for stress-reduction training for all employees involved in high-stress activities.
- c. Gives particular attention to reducing stress in inexperienced, naive, and highly emotional employees and students before and during studies.

5. **Maintains a scholarly, sensitive, and respectful environment and behaves in a professional manner.**
6. **Endeavors to build and maintain public confidence in animal research.**
  - a. Provides a lay-language description of studies and procedure for the IACUC and for other institutional purposes.
  - b. Might participate in community programs to promote understanding the need for and role of animals in research, testing, and teaching.

### **III. REVIEW OF ANIMAL USE**

#### **A. Circumstances Requiring IACUC Review of Animal Use**

Before any live **vertebrate** animal can be used in research, training or teaching, the proposed animal use must be reviewed and approved by the IACUC, regardless of the project's funding source. It should be stressed that the animal regulations require the IACUC to consider a number of specific aspects of animal use in the context of a particular research or teaching project. These are discussed more at length in Appendix A. For this reason, an approved protocol covering a particular procedure cannot be used for another project with a different objective simply because the animal procedure is the same, although reference to approved standard operating procedures can simplify the review and approval process.

A completed Application for Animal Care and Use must be submitted under any of the following circumstances where live **vertebrate** animals may or will be used:

1. All funded federal grant applications that involve the use of vertebrate animals.
2. All activity on-campus using vertebrate animals.
3. All activity off-campus done by CSUF students, faculty or staff using live vertebrate animals. Off-campus work at another institution must also have approval from that institution's IACUC.

Any activity that will affect the animals in CSUF's care (e.g., remodeling, public display of animals) should also be brought to the IACUC's attention.

#### **B. Exemptions**

The following activities are exempt from the requirement for a Protocol for Animal Care and Use. Requests for exemptions should be done through a memo sent to the IACUC Chair. This is reviewed and approved by the Chair.

1. Use of dead animals or tissue from dead vertebrate animals. However, persons collecting carcasses must have the appropriate state or local permits, and persons

using dead lab animals must verify that the animals were not sacrificed for their project.

2. Non-invasive observations of wild animals in their natural habitat that do not harm or materially alter their behavior. However, **field studies that involve capturing, killing, banding, darting or implantation of telemetry devices are NOT exempt, nor are field studies of threatened or endangered species.**
3. Work done by a CSUF investigator at another institution, not using funds procured or managed by CSUF, and not doing the work for CSUF credit, a project or a thesis.
4. Procurement of custom antibody or tissue products from USDA-approved commercial sources. However, the contractor must have a current NIH Assurance and be USDA-registered as a research facility. The contractor must certify and provide evidence (e.g., approved protocol) that all procedures will be done in compliance with federal regulations governing the ethical care and use of animals, and that CSUF IACUC will be notified promptly of any problems related to animal care and use for the project.

### C. Specific Considerations for Federal Grant Applications

1. Grant Applications: Federal regulations require documented approval of animal protocols for federally funded projects. Whereas most NIH grant applications allow for a 60-day grace period between the grant submission deadline and the animal protocol approval, in some situations, the protocol must be approved by the grant submission deadline. Funding sources other than NIH may also require that the animal protocol is approved before the grant application can be submitted.

In the case of program grants with multiple projects, the Program Director should ensure that each project or component of the proposal involving vertebrate animals is reviewed by the IACUC. The Program Director should contact the individual project investigators or the IACUC Coordinator for information on protocols and approval dates.

ORSP can help investigators determine the appropriate agency requirements. Principal Investigators who have questions about their approval dates or whether a particular protocol covers work under a grant should contact the Coordinator.

Please note that federal regulations also now require documented annual review of approved animal protocols, as well as the review and approval of modifications to on-going animal use.

2. NIH, NSF and other grant agencies may require a description of proposed animal activities or changes in existing projects as part of their grant applications or

progress reports, in addition to annual approval documentation. It is the investigators' responsibility to be aware of these requirements. Investigators may seek assistance on this matter from ORSP.

3. Collaborative Research with Other Institutions: If funds will be awarded through CSUF, investigators should submit a completed Application for Animal Care and Use, irrespective of the site of the proposed animal use. In addition, if animals in the proposed collaborative research will be used at another institution, such animal use must be reviewed and approved by the other institution's IACUC. Contact the IACUC Office for advice on whether a Memorandum of Understanding (MOU) agreement between collaborating institutions can be used as an alternative to having to duplicate IACUC reviews at multiple campuses.
4. Materials From Commercial Sources: PHS-funded investigators using antibodies custom-made from other sources must ensure that the source has a valid NIH Assurance and have been approved by the USDA. The contractor must also provide evidence (approved protocol) and certify that all procedures will be done in compliance with federal regulations governing the ethical care and use of animals, and that CSUF IACUC will be notified promptly of any problems related to animal care and use for this project.

## IV. APPLICATION PROCESS

### A. Application and Review Process

Submission and review of applications for animal use are done online via **Cayuse IACUC** (also called Cayuse Animal Oversight), which is accessible from the Research Compliance webpage (<http://www.fullerton.edu/doresearch/compliance/iacuc.php>). PIs should seek training on how to use Cayuse IACUC from the IACUC Office well in advance of submitting materials.

1. Application: The application for animal use should be completed by the responsible faculty member (Principal Investigator, faculty sponsor or advisor, or course instructor), not a student or staff member. This application is also known as a Protocol. The information given must be complete, as it forms the basis for IACUC review and approval. Protocols are also subject to scrutiny by site visitors from NIH and by inspectors from the USDA.

Investigators who are proposing work involving biohazards, controlled substances, radiation and radioactive isotopes, and zoonotic disease potential, must consult with the appropriate safety officer before completing their protocol application (such work may require approval from the [Institutional Biosafety Committee](#)). PIs submitting protocol applications that involve potential risks to human workers must identify such risks on the application. These will be evaluated as part of the IACUC review process and approved protocols will be

forwarded to the appropriate EH&S staff. All activities conducted off-site require permission from the hosting location for those activities.

Because of intimate and highly individualized nature of most research projects involving animals, most training in the safe and humane use of animals will necessarily be hands-on, and conducted by an experienced PI, the Animal Care Facility Specialist, or the Campus Veterinarian. However, it is essential that all researchers and instructors working with animals understand the key principles, policies, and responsibilities that are involved with animal-related research and teaching. Toward that end, all investigators listed on an IACUC protocol must complete the online CITI training module entitled “*Using Animal Subjects in Research*” (ID: 13301). Furthermore, all trainees, i.e., students and postdoctoral researchers, who are working on federal NIH and NSF grants must also complete the required modules in the “RECR - Responsible and Ethical Conduct of Research”. Instructions for accessing the CITI modules are on the ORSP website [http://www.fullerton.edu/doresearch/compliance/iacuc\\_compliance\\_training.php](http://www.fullerton.edu/doresearch/compliance/iacuc_compliance_training.php). At its discretion, the IACUC or the Animal Care Facility Specialist may require additional online or hands-on training, depending on the project.

Evidence of successful completion of the appropriate training modules (normally, a Completion Record or Certificate available from CITI) must be submitted for all listed investigators at the time of submission of a new or continuing IACUC protocol application. **A Protocol cannot be approved until all certificates have been received by the IACUC Office.** CITI training must be renewed every four years. The PI on a project or course is responsible for ensuring that all researchers working with animals under their supervision have the appropriate and updated training.

Because exposure to animals poses a potential health risk to some individuals, anyone handling animals or animal tissues must complete an Animal Handler Referral Form, detailing their health history. This information is reviewed by a medical health professional under contract with the Office of Environmental Health and Safety (EHS), which coordinates with IACUC to implement the Animal Care and Use Occupational Health program. The PI of the proposed project must first complete an Animal Handler Job Duties form that describes the type of work to be done and identified potential risk. **A protocol cannot be approved until all individuals have been cleared by EHS to work with animals.** Medical clearance may need to be renewed annually or every three years, depending on the degree of risk and exposure as identified by the medical health professional’s review.

Investigators working with captive animals should consult with the Animal Care Facility Specialist regarding available facilities and proposed procedures before completing their applications. The IACUC cannot approve a protocol unless appropriate facilities are available for the number and species of animals requested.



Investigators are ***strongly encouraged*** to make a draft of their protocol application available to the IACUC Chair for informal pre-review through Cayuse IACUC **prior to** submitting it for review.

2. **Review of Application:** Upon receipt of the application in Cayuse IACUC, it is assigned a protocol number and then sent by the IACUC Office to IACUC members for review and comment. The IACUC members will review the protocol based on the criteria mandated by federal regulations and the more specific guidelines referenced in Section I, Part D above. Clarification or further information may be requested from the PI via the Coordinator. If the committee is satisfied with the protocol, it votes to approve it. Final rejection of a protocol is unusual; in the most cases, the committee's concerns can be resolved in communication with the PI, although it may require a second or even third round of reviews.
3. **Approval:** After the protocol is approved in Cayuse IACUC, the PI is notified by email. Notification of approval is also sent to the Animal Care Facility Specialist, the Institutional Official, Campus Veterinarian, and the Chair of the PI's Department. Protocols are usually approved for three years but a Continuing Review report must be submitted annually.
4. **Amendments:** A request to modify an approved protocol must be submitted through Cayuse IACUC when there is substantial modification to an approved protocol. Substantial changes in an on-going project may include a) the use of more animals than the number originally estimated, b) use of additional species, c) use of new procedures, d) use of new hazardous agents or procedures that increase risk to human health and safety, and e) addition or deletion of personnel (NOTE: Cayuse IACUC only allows deletion of personnel during annual reviews, not amendments; contact the IACUC Office if you have questions). Changes to personnel may be done administratively, i.e., without full committee review, but all new personnel must provide evidence of training and medical clearance before they can begin work. **All modifications must be approved prior to the start of the proposed changes.** The IACUC reserves the right to request the submission of a new protocol application whenever changes to an approved protocol are so significant that the original protocol no longer reflects the current animal usage or project objectives.
5. **Continuing and De Novo Review:** Approved protocols must be reviewed annually (Continued) to remain valid. The protocol may be continued with minimal review two times, for a maximum protocol duration of three years from the original approval date. The Continuation form requires a brief progress report, including animal use, and information about changes in the protocol. A De Novo application must be submitted for a full review if an on-going animal project is to be continued past the third anniversary of the protocol approval date. When a project is completed, the PI must initiate the closure of the protocol in Cayuse.



6. **Review and Approval of Renewal:** The PI will be notified by the IACUC Coordinator via email from Cayuse IACUC when an approved protocol is due for a Continuation and also when an approved protocol is at the end of the third year and a De Novo application may be needed. The PI is responsible for renewing any ongoing protocols in a timely fashion to ensure that approval of animal use is continuous. The De Novo application will be reviewed as a new protocol, although the same reviewers may be used. The most recent approval date, rather than the original approval date, must be used on all grant applications.

## **B. Significance of the IACUC Protocol Number**

Each animal protocol describes animal use in a specific project and is identified by an IACUC protocol number and version number. This number is used to identify the project on all forms and correspondence. It is important to keep the protocol number and approval date on file. The protocol number also appears on the animal's cage card. It is used by site visitors and inspectors from NIH and USDA, as well as by the IACUC, to access the approved protocol for clarification regarding on-going animal use.

## **C. Protocol Contents**

PHS Policy and the Animal Welfare Act and University regulations require that protocols and supporting documentation include specific information. Listed below are the major points which must be included in applications covered under this regulations and under University policy.

1. Identification of the species and the estimated number of animals to be used.
2. A rationale for involving animals and for the appropriateness of the species and number of animals.
3. A complete description of the proposed use of animals.
4. A description of the animals' living condition appropriate for their species and contributing to their health and comfort.
5. An assurance that medical care for animals will be available and provided as necessary by a qualified veterinarian.
6. A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals (include dosage and route).
7. A description of any euthanasia method to be used.
8. A complete description of how personnel conducting the procedures have been or will be appropriately qualified and trained in those procedures to ensure safety to animals and to faculty, staff and students involved in research.

9. A description of any unusual risks to human health or safety that are directly related to the use of animals.
10. An assurance that the PI has adequately considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals.
11. A written assurance that the activities do not unnecessarily duplicate previous experiments.

## **V. USE OF ANIMALS ON- and OFF-CAMPUS**

### **A. Ordering Animals**

All arrangements for acquiring and housing live vertebrates from any source must be made through the Animal Care Facility Specialist; arrangements for housing must be made before an order will be placed. Animals may not be purchased or otherwise acquired until a fully approved protocol is on file and the Animal Care Facility Specialist is notified. If exotic or other animals from nature are to be used, arrangements for any necessary quarantine must be made through the Animal Care Facility Specialist before animals are acquired. The investigator is responsible for determining if permits (such as U.S. Fish and Wildlife Service or California Department of Fish and Wildlife) are required, and any necessary permits must be obtained before animals are acquired. The Animal Care Facility Specialist can help investigators to determine whether permits are needed and assist in obtaining them.

### **B. Animal Housing**

Campus practices in the housing and care of animals must conform both to the “Guide for the Care and Use of Laboratory Animals” and to USDA regulations. These documents set forth detailed guidelines for animal care and use in research. Copies of these documents can be obtained from the ORSP Resource Library under [Policies & Guidelines](#) website. The IACUC may not approve projects involving animals for which CSUF does not have adequate housing.

Housing animals in CSUF facilities may incur per-diem charges. Investigators submitting grants should include these charges as part of the grant application. Current rates are available from the Animal Care Facility Specialist.

Animals shall be housed only in facilities inspected and approved by the IACUC. Animals removed to non-inspected areas (e.g., laboratories) for teaching or research purposes must be returned to an approved holding facility within 12 hours. Animal housing rooms are to be used for housing of animals only. Research equipment must not be stored and procedures must not be done in the housing room without special permission from the IACUC.

## **C. Animal Identification and Record Keeping**

### **1. Animal Identification**

The USDA regulations and NIH Guide require appropriate identification of animals and maintenance of records. Accepted methods of animal identification include room, rack, and cage cards; collars and bands; ear notches and tags; implantable microchips; tattoos, etc. Toe clipping is acceptable only for infant rodents and lower vertebrates when other methods of identification cannot be used, and must be specially approved by IACUC in advance.

### **2. Cage Cards and Record Keeping**

Cage cards supplied by the Animal Care Facility Specialist have been designed to satisfy the Animal Welfare Act requirements. Research or other data may be placed on the back of this card or on a second card in the holder behind the identification card. However, the completed cage card must be visible on all animal cages at all times.

Investigators are responsible for maintaining, and updating, appropriate cage card records on rabbits and rodents. Cage or rack cards should indicate, at a minimum, the protocol number, the source of the animal, strain or stock (if pertinent), and names of responsible investigators. Written records of procedures, drug use, illness and injuries, and date of death, euthanasia, or disposition should be noted on the cage card. Animal staff monitor the animals and their respective cards on a daily basis -- the importance of maintaining and updating the cards cannot be emphasized enough.

These records also serve as a means of communication between the investigator and animal care personnel. All animal manipulation and drug use, as well as objective observations on health status, should be recorded by both animal user and animal care personnel.

All animal records must be maintained for three years and are subject to inspection by the USDA, granting agency (NIH, NSF and others) site visitors, and the IACUC.

### **3. Approved Protocol**

All personnel should be aware of the location of the approved protocol, as it may be requested by federal or IACUC inspectors. A copy of the approved protocol should be available to be given to appropriate investigative personnel, if requested, but should not be shared with others without the written permission of the PI.

#### **D. Routine Care**

The Campus Veterinarian and designee, the Animal Care Facility Specialist, are responsible for monitoring animal care and use practices and for providing advice and assistance to investigators in the correction of any deficiencies with respect to conformance with applicable policies, laws, and regulations. Any issues of disagreement between animal users and the Veterinarian or Animal Care Facility Specialist shall be referred to the Chair of the IACUC.

#### **E. Emergency Care**

Any animal health problem noted by anyone at any time, including evenings, weekends and holidays, should be immediately reported to the Animal Care Facility Specialist or animal care personnel. An alternate contact would be the University Police, who will then attempt to make contact with the Animal Care Facility Specialist.

The Animal Care Facility Specialist must also be notified immediately of facilities malfunctions (e.g., excessively hot or cold animal rooms) or remodeling that may directly threaten animal health. In the event of a campus-wide emergency, the Animal Care Facility Specialist will work with the Campus Veterinarian, project PIs, and other campus authorities to make decisions about how to ensure the appropriate care of animals in animal facilities, given the circumstances and resources available (see Disaster Plan).

#### **F. Transportation of Animals on Campus**

Animals should be transported in approved cages that will prevent their escape and minimize stress. Carrying the animals in one's arms or in open boxes is not acceptable. For transportation of rodents to other buildings on campus, it is recommended that micro-isolator cage units be used whenever possible.

In planning the route by which animals will be transported between laboratories and the animal housing areas or other laboratories, care should be taken to minimize time spent in public areas, including common hallways or lobbies. Passenger (non-freight) elevators should be avoided if at all possible. Efforts must be taken to reduce the amount of stress the animal undergoes while being transported, and minimal exposure of the animals to unfamiliar areas will be beneficial. Moreover, any additional stress may add an unwanted variable to a research project. Minimizing time spent in public areas also reduces unwanted attention to the use of animals on campus, which represents a potential security risk.

#### **G. Removal of Animals from Campus**

Animals used for teaching and research are the property of CSUF. No animal or animal carcass shall be removed from or brought onto University property, except in

accordance with established campus procedures or with prior approval of the Animal Care Facility Specialist.

Animals may not be removed from this institution without prior specific permission from the Animal Care Facility Specialist, the Campus Veterinarian or the IACUC. When animals are to be shipped, all shipments, regardless of whether or not they are to be returned, must be coordinated through the Animal Care Facility Specialist to ensure that proper health certificates (federal and/or state) are completed. The Animal Care Facility Specialist, after consulting with the Campus Veterinarian, will make the necessary shipping arrangements, and will see to it that approved shipping containers are used.

#### **H. Waste Disposal**

Radioactive and other biohazardous carcasses and animal wastes must be disposed of according to procedures established by the Office of Risk Management and Environmental Health and Safety (EH&S). All other animal carcasses should be disposed of per EH&S guidelines as well.

#### **I. Reporting and Dealing with Deficiencies in Animal Care and Treatment or with Non-compliance**

Any complaint or concern by faculty, staff or students regarding either the care and use of animals in instruction or research or charges of animal abuse at CSUF should be directed to one of the persons listed below, either verbally or in writing.

1. the Principal Investigator or their Department Chair
2. the Chair of the CSUF IACUC (657-278-2849)
3. the Animal Care Facility Specialist (657-278-5388)
4. the Campus Veterinarian (949-855-9744)
5. the IACUC Coordinator (657-278-7719)

See [http://www.fullerton.edu/doresearch/compliance/iacuc\\_animal\\_concerns.php](http://www.fullerton.edu/doresearch/compliance/iacuc_animal_concerns.php).

Complaints and concerns will be kept anonymous (name is not known) or confidential (name is not revealed), if requested. Anonymous complaints will be investigated, but are generally less effective.

All complaints and concerns shall be identified as such, shall be forwarded to the IACUC Chair as soon as possible, and shall be dealt with using the following procedure:

The IACUC Chair\* shall contact the PI of the protocol in question, the complainant (if known), the Institutional Official, and, if necessary, other individuals, and then shall report to the IACUC on whether a tentative resolution has been reached. If the resolution is satisfactory to a majority of the IACUC members, the complaint shall be considered settled and the IACUC Chair will send a letter to the PI confirming that the issue was discussed and confirming the resolution. If the complaint cannot be

resolved in such a manner, the compliance monitoring subcommittee may investigate the matter further. A formal letter outlining the IACUC's concerns shall be sent to the PI by the IACUC Chair, with a copy to the Institutional Official, and a written response shall be made by the PI to the IACUC within a specified time period. The IACUC shall review the response and propose a resolution. If a resolution cannot be found, the protocol may be suspended. PIs have the right to request an appeal to the Institutional Official. The Institutional Official shall be kept informed about all complaints and how the IACUC resolved them. Once the final resolution is reached, the complainant (if known) will be informed that the matter has been addressed by the IACUC and resolved.

*\* If the complaint or concern is directed against the IACUC Chair, the Institutional Official will be asked to appoint another member of the IACUC compliance monitoring subcommittee to coordinate the investigation.*

In addition,

The Veterinarian and the IACUC have the power to immediately suspend a protocol if the welfare of study animal(s) are being endangered.

If an activity or protocol is suspended by the IACUC, a Suspension Report must be filed with USDA and/or NIH by the Institutional Official, in consultation with the IACUC, as detailed in the NIH *"Institutional Animal Care and Use Committee Guidebook."* A Suspension Report contains a full explanation of the circumstances involved and a description of corrective actions, and may include minority reports.

In the case of Non-compliance ("procedures or policies are not being followed") that constitutes serious deviation from the NIH *Guide* or serious or continuing non-compliance with federal and CSUF policy, the IACUC shall recommend to the Institutional Official that a Non-compliance Report be sent to NIH, as detailed in the NIH *"Institutional Animal Care and Use Committee Guidebook."* A Non-compliance Report contains a full explanation of the circumstances involved and a description of corrective actions, and may include minority reports.

## **VI. SPECIAL SITUATIONS**

### **A. Field Studies**

The IACUC is responsible for ensuring the protection of animals used in field studies of live vertebrates. IACUC review and approval is not required for field studies conducted on free-living, wild animals in their natural habitat as long as the activity is non-invasive and does not harm or materially alter the behavior of the animal. However, PIs of such studies must contact the IACUC Chair in advance of beginning work to ensure that their intended use of animals is not subject to full IACUC review and to formally request an exemption. Exemption memos are kept on file in the

IACUC Office and may be necessary to verify to other authorities and publishers that their activities were in compliance with University (and therefore federal) guidelines. Note that field studies involving threatened or endangered species are not exempt from IACUC review.

Professional field biologists in scientific organizations devoted to the study of fish, amphibians, reptiles, birds, and mammals have prepared guidelines for field work with these animals, which are a useful reference. The most recent *AVMA Panel on Euthanasia* provides guidance on acceptable methods of euthanasia for wild animals. Copies of these guidelines are available on the CSUF IACUC website [http://www.fullerton.edu/doresearch/resource\\_library/policies\\_and\\_guidelines.php](http://www.fullerton.edu/doresearch/resource_library/policies_and_guidelines.php).

#### **B. Live Display Animals**

Under approved circumstances, live vertebrate animals may be kept for display purposes in classrooms or laboratories. These animals must be covered by animal care and use protocols and are covered by the same regulations as lab animals. A master protocol is maintained for the species routinely used in biology or related courses.

#### **C. University Vertebrate Museums/Collections**

The acquisition and/or donation of preserved specimens and/or "road kill" animals does not require the filing of a protocol. However, dead vertebrate museum specimens, acquired either by collection or donation from other sources, must comply with established museum regulations mandated by federal and/or state authorities. The acquisition of any live vertebrate specimens brought on campus for contribution to museum collections must have approval of the IACUC.

#### **D. Pets On-campus in Animal Facilities, Labs or Offices**

CSUF is a workplace and a learning space. For the safety, comfort, and well-being of people and animals used legitimately on campus, pet animals (including dogs but also rabbits and rodents) are not allowed anywhere on campus, in animal facilities, laboratories, or offices. Designated service dogs are permitted on campus under policies described by Disability Support Services (DSS) [https://www.fullerton.edu/dss/faculty\\_staff/serviceanimals.php](https://www.fullerton.edu/dss/faculty_staff/serviceanimals.php). Residents of on-campus housing may obtain special, prior approval from DSS on a case-by-case basis to keep an emotional support animal, but these animals must remain inside on-campus housing.

### **VII. HAZARDS / SECURITY**

#### **A. Biohazards, Controlled Substances and Radiation Safety**



Principal Investigators are responsible for maintaining compliance with all federal, state, local and campus regulations regarding these areas. Investigators should consult with the appropriate EH&S safety officer for planning and to receive training. Investigators should also ensure that all personnel working on a teaching or research project are appropriately trained and have the appropriate equipment for the hazard(s) related to a specific project. Work involving such hazards must be approved by the CSUF Biosafety Committee.

## **B. Animal Bites or Other Animal-Related Injuries**

In the event of an animal bite or other animal-related injury, administer first aid (follow designated protocol or wash the wound thoroughly with soap and water) and report the injury promptly to the designated person (supervisor, instructor, employer, etc.) in charge and to the Animal Care Facility Specialist. Report to the Student Health Center on campus if additional treatment is deemed necessary by the designated person in charge. Additional information is in the CSUF Animal Care and Use Occupational Health Program.

In the event of an animal bite after-hours and/or on weekends, call the Animal Care Facility Specialist, or University Police (who will contact the Animal Care Facility Specialist). Clean the wound as noted above. Report to an emergency medical facility if further treatment is necessary. Inform the physician as to the nature and situation of the injury.

Complete either the **CSUF Employee Accident Report** form or the **CSUF Student and Visitor Accident Report** form and submit it to the designated person, who is required to submit the form to the respective authorities indicated on the form within 24 hours.

If the animal is still alive, it should not be destroyed. It should be placed in quarantine and the Campus Veterinarian notified. If the animal is dead, tissues will be collected and may be submitted to the proper authorities for further evaluation. Under most circumstances, rabbits and rodents raised for research purposes do not need to be quarantined.

## **C. Zoonotic Diseases**

Certain diseases can be spread from animals to humans and the reverse. Hepatitis A and B, Herpes B, tuberculosis, rabies, plague and hantavirus are examples of diseases that can be spread from animals to humans. Appropriate training and precautions should be taken. Those at risk are required to participate in the campus Occupational Health Program. A list of animals and zoonotic diseases is available from EH&S. Additional information on this topic is also in the CSUF Animal Care and Use Occupational Health Program.



## D. Security

Security measures have been established to protect the animals used in instruction and research at CSUF. Cooperation from all concerned in enforcing these measures is essential.

### 1. Entrance into Animal Housing Facilities

Entrance into all animal facility rooms is subject to the authorization of the Animal Care Facility Specialist and the Campus Veterinarian. Under no circumstances are students, staff, or faculty to give tours through the animal facilities without the consent and authorization of the above persons. Individual rooms within the animal facilities will be secured by key and kept locked at all times. The Animal Care Facility Specialist will initiate key request cards to individual faculty and staff who need to gain entrance. **Keys should never be loaned. It is a criminal offense to duplicate any keys to the animal facilities, as well as any other building or room at this institution.**

### 2. Visitors

In an effort to protect animals and minimize any possibility of disease transmission, visitors -- including family members and friends -- are not allowed in animal facilities without prior approval by the Animal Care Facility Specialist. Tours of the animal facilities may be requested and will be conducted by the Animal Care Facility Specialist or the Campus Veterinarian at their discretion.

### 3. Photography, Video- or Audio-recording of Animals

The use of live animals in instruction and research is a sensitive and emotional issue. Photography may also cause stress to the animals (people, equipment, light, etc.). Therefore, all plans to photograph or otherwise record animals on campus must be authorized and reviewed by the Animal Care Facility Specialist. **Under no circumstances should photographic equipment be taken into animal facilities without the specific prior approval of the Animal Care Facility Specialist or the Campus Veterinarian.** When photographing, video-recording or audio-recording is proposed for research or instructional purposes, the PI must include in the protocol application a scientific justification for photographing, video-recording and or audio-recording; information on the duration of the recording, including whether such recording will be monitored remotely; and if continuous video-recording is requested, a description of how potential disruption to animals' sleep schedules or behavior will be addressed. All photographs, video and audio-recordings (including copies) must be securely destroyed when they are no longer required for the approved activity.

Instructors must exercise caution when allowing photographs of any instructional exercise(s) involving animals. Photographers are urged to consider all possible interpretations of pictures of animals taken for documentation or publication. Every effort must be made to show appropriate and accurate context when images or recordings are acquired, including compliance with approved care, handling, and restraint procedures. Photographs, video and/or audio-recordings of animals in animal facilities must not be posted to any type of media or website, including laboratory websites, unless expressly permitted by the Animal Care Facility Specialist, IACUC Chair, and, if relevant, the project PI.

#### **4. External Inquiries Regarding Animal Use**

Faculty, staff and students should not attempt to answer questions from individuals not affiliated with CSUF regarding animal care and use at this institution. All questions should be referred to the Animal Care Facility Specialist, the Campus Veterinarian, or the IACUC Chair. Inquiries from members of the media should be directed to the Office of the Associate Vice President for Academic Affairs, who will clear interviews with CSUF faculty and staff. The Animal Care Facility Specialist and IACUC Chair should be kept informed of all such requests for information and, when possible, provided with the name, address, telephone number, and affiliation of the individual(s) making the inquiry. The Animal Care Facility Specialist, the Campus Veterinarian, IACUC Chair, or other designated personnel informed on the issues will answer questions from individual(s) and explain the institutional policy on the care and use of animals.

#### **5. Threats Related to Animal Use**

All CSUF faculty, staff and students, and all animal care personnel should **immediately** report all threats, whether written or verbal, to the University Police and the Animal Care Facility Specialist. The University Police will advise threatened individuals on security measures, and will otherwise take action the Director of Public Safety deems appropriate.

#### **6. Demonstrations**

In the event of a demonstration on campus related to instructional or research animal use, all CSUF personnel should avoid any activity that would jeopardize the health and safety of the animals, avoid any action that may result in or encourage belligerence or the disruption of routine animal care activities, and follow the directions of the public safety personnel.

#### **7. Break-ins, Theft, and/or Acts of Vandalism**

Anyone discovering a break-in, theft, and /or act of vandalism in any animal housing area or animal support area should inform the University Police

**immediately**. University Police will notify the Animal Care Facility Specialist and the Institutional Official. The area should not be cleaned or otherwise disturbed until permission is received from the individual responsible for the investigation.

## **VIII. SUPERVISION AND TRAINING**

### **A. Supervision and Training**

Both PHS Policy and the USDA regulations require that all personnel involved in the care and use of experimental animals receive appropriate instruction in humane care and use concepts and proper animal handling. Supervisors of persons involved in the care or use of animals shall be responsible for providing adequate supervision and training to ensure conformance with occupational safety practices, animal care regulations, and accepted experimental techniques.

To this end, the mandatory online [CITI Program](#) training course “*Using Animal Subjects in Research*” and this handbook provide general information on laws, policies and procedures related to animal care and use, and to policies and procedures specific to CSUF. Specialized training in specific animal procedures, or with certain animal species, is available from the Animal Care Facility Specialist. General lab safety training is provided by EH&S. Training in the following areas is mandatory for all personnel identified in an approved protocol.

- Area 1 Animal Welfare Act, general CSUF Policies and Procedures
- Area 2 Specific animal/procedure training
- Area 3 Safety training

Training must be documented in a central location where it is available for inspectors from federal, state or local regulatory agencies. Training documentation should include the name of the trainer, the name and signature of the trainees, the content of the training, and the date the training took place.

### **B. Students in Classes**

Some courses or laboratories may use animals for instructional purposes. Students must be informed at the beginning of the course that animals will be used for instructional purposes and be informed of the nature of the work and their options for participation. The IACUC has established the following guidelines for use of live animals in laboratory courses:

1. Animals shall be handled according to the procedures described in the approved IACUC course protocol, and follow accepted guidelines, such as the *Guide for the Care and Use of Laboratory Animals*, to minimize pain and suffering, and with proper anesthetic procedures where appropriate. Guides are available at the ORSP website:

[http://www.fullerton.edu/doresearch/resource\\_library/policies\\_and\\_guidelines.php](http://www.fullerton.edu/doresearch/resource_library/policies_and_guidelines.php).

2. Efforts will be made to minimize the number of animals needed for any study or experiment in which any kind of pain, suffering or death is involved.
3. Students will not be forced to euthanize the animals used for experiments in courses.
4. The instructor has the responsibility to consider student objections to working with animals.
5. Announcements will be made at the beginning of the course and in the course syllabus if the coursework requires manipulating live animals and/or live animal tissue.

### **C. Occupational Health and Safety**

All CSUF and ASC employees, including course TAs and GAs, students, and volunteers who work with animals or animal tissues as a condition of their employment should be aware of the precautionary health measures that are recommended for their situation. All employees, students, and volunteers must be properly alerted to any risks associated with animal contact in their research, teaching or animal husbandry situation. All employees must be properly equipped and trained. Guidelines for working with specific types of animals may be obtained from EH&S, the Campus Veterinarian, or the Animal Care Facility Specialist.

All individuals listed as animal handlers on an IACUC protocol must provide evidence to the IACUC Office that their Medical Health Questionnaire has been reviewed and approved and that it is up-to-date, following the steps described in the Animal Care and Use Occupational Health Program.

## APPENDIX A

### U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires *in vivo* experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable general laws, guidelines, and policies.
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by the Institutional Animal Care and Use Committee, or a subgroup thereof. Such exceptions should not be made solely for the purposes of teaching or demonstration.